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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,291	10/14/2005	Mary J. Eaton	US 1442/05(VA)	8630

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EXAMINER	
GAMETT, DANIEL C	

ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
12/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,291	EATON, MARY J.	
	Examiner	Art Unit	
	DANIEL C. GAMETT	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23,25 and 27-29* is/are pending in the application.

4a) Of the above claim(s) *1,3,5-8,17-23 and 25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,4,9-16 and 27-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 October 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :10/14/2005, 08/16/2006,04/26/2007.

DETAILED ACTION

1. Applicant's election with traverse of claims 2, 4, 9-16, 24, and 26 in the reply filed on 10/12/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

   The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1, 3, 5-8, 17-23, and 25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/12/2007.

3. The amendments of 10/12/2007 have been entered in full. Claims 24 and 26 are cancelled. Claims 2, 4, 9-16, and 27-29 are under examination insofar as they read upon to GABA expressing NT2 cells, and methods of treating neurological disease comprising administering GABA expressing NT2 cells.

Claim Objections

4. Claims 13-16 are objected to because of the following informalities: The claims are drawn to nonelected subject matter. The claims are drawn non-elected methods that do not require the elected GABA expressing NT2 cells. Specifically, claims 13-16 recite methods that require only administration of a cell expressing serotonin. Applicant is required to

cancel or amend the claims to remove nonelected subject matter. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 9-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The fact that a patent is directed to method entailing use of a compound, rather than to the compound *per se*, does not remove patentee's obligation to provide description of the compound sufficient to distinguish infringing methods from noninfringing methods (University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 (CAFC 2004)). In this case, the claims are drawn to methods that comprise administration of a genus recited as "a cell transplant material". To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination

thereof. In this case, the specification only discloses that a cell transplant material may comprise serotonin expressing human NT2 cells or gamma-aminobutyric acid (GABA) expressing human NT2 cells ([0024-0025] of the published application). An exemplary list is not a definition. "A cell transplant material" could be any material; the genus is limited only by a proposed use. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

7. With the exception of serotonin expressing or GABA expressing human NT2 cells, the skilled artisan cannot envision the the encompassed materials, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.
8. Therefore, only serotonin expressing or GABA expressing human NT2 cells, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph.

9. Claims 27 and 28 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The invention employs novel biological materials, specifically

the cell deposited as ATCC Designation No. PTA-7154. Since the biological materials are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. If the biological materials are not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the biological materials. Applicants' referral to the deposit of hNT2.17 cells under Accession No. PTA-7154 on page 32 of the specification is an insufficient assurance that all of the conditions of 37 CFR sections 1.801 through 1.809 have been met. The specification does recite the date of the deposit, the complete name and address of the depository, and the accession number of the deposited cell line, as required. However, there is no indication in the specification as to public availability. As the deposit was made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicants, assignees or a statement by an attorney of record over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that *all restrictions upon public access to the deposits will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required.* This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves these specific matters to the discretion of each State. Applicants amendment to the specification and Applicant's Declaration, both filed 08/31/2006, do not provide the emphasized assurances. See 37 C.F.R. § 1.806-1.808.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 2, 9-14, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 6254865 (Freed), July 3, 2001 (of record). Freed teaches treatment of neurological disease by transplantation of hNT cells, which are neurons derived from NT2 cells (column 26, lines 20-33). Freed further teaches that hNT cells differentiate into GABAergic neurons (column 18, lines 12-17; FIG.2)). Transplantation into the brain and spinal cord are taught (column 24, lines 38-60), as well as treatment of all of the presently claimed diseases (column 21, lines 8-23).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 4, 15, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6254865 (Freed), July 3, 2001, as applied to claims 2, 9-14, and 29 above, and further in view of US Patent 5449609, September 12, 1995 (Younkin) and US 5175103 (Lee), December 19, 1992 (of record). As noted, Freed teaches isolation of GABA expressing human NT2 cells and treatment of all of the presently claimed neurological diseases by transplantation of hNT cells into the brain and spinal cord. Freed does not, however, specifically teach cloning of GABA expressing human NT2 cells as required by instant claims 4, 15, and 16. The Freed reference indicates that the desired phenotype of producing GABA is present among NT2 cells differentiating in the presence of retinoic acid. Freed obtained the GABAergic cells by mechanically separating differentiated cells from undifferentiated cells (column 22, lines 20-26, citing Patent 5,654,189 (Lee)). The NT2 cell line was first derived by cloning from an immortal cell line (Lee, column 2, lines 28-54 and references cited therein) and is known to be amenable to subcloning (Lee, column 12, lines 48-57; column 14, lines 15-26). These properties are recognized as being advantageous for manipulation and isolation of a homogenous population of cells displaying a desired neuronal phenotype (Younkin, column 5, lines 31-47. Therefore, one of skill in the art at the time the instant application was filed would expect that inclusion of a cloning step into the method taught by Freed would yield clones of GABA expressing cells. Therefore, the methods recited in claims 4, 15, and 16 are prima facie obvious over the method of Freed because the cloning limitation of the instant claims represents simple substitution of one known element for another to obtain predictable results.

Conclusion

14. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel C. Gamett, PhD., whose telephone number is (571)272-1853. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571 272 0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DCG
Art Unit 1647
18 December 2007

/David S Romeo/
Primary Examiner, Art Unit 1647